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EXAMINER	
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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KEITH E. JASPERSON, THOMAS J. VALINE, and FREDERIC J. R. WAHLQUIST

Appeal 2009-008831
Application 10/809,157
Technology Center 3700

Before: WILLIAM F. PATE III, JENNIFER D. BAHR, and LINDA E. HORNER, *Administrative Patent Judges*.

BAHR, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 1-13. We have jurisdiction under 35 U.S.C. § 6(b).

THE INVENTION

Claim 1, reproduced below with added emphasis, is illustrative of the claimed subject matter:

> 1. A method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional, said implanted device being part of a system, comprising the steps of:
>
> *manually programming* said implanted device with a maximum dose, a basal rate and *a plurality of interval rates over a specified period of time*, each individual one of said interval rates corresponding to an individual one of a plurality of time slots during said specified period of time;
>
> *said system determining a total dose over said specified period of time based* on said basal rate and *said interval rates*, each individual one of said interval rates corresponding to an individual one of said plurality of time slots;
>
> said system adjusting said basal rate so that said total dose does not exceed said maximum dose; and
>
> delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates specified in said programming step.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Fischell	US 4,731,051	Mar. 15, 1988
Boydman	US 5,069,668	Dec. 3, 1991
Hartlaub	US 2001/0037083 A1	Nov. 1, 2001

REJECTIONS

I. Claims 1-7 and 9-13 are rejected under 35 U.S.C. § 102(e) as anticipated by Hartlaub.

II. Claims 1-13 are rejected under § 102(b) as anticipated by Fischell.

III. Claims 1-10, 12, and 13 are rejected under § 103(a) as unpatentable over Boydman and Fischell.

SUMMARY OF DECISION

We REVERSE.

ISSUE

In relevant part, independent claims 1 and 13 recite a method of delivering fluid medication from an implanted device that is part of a system, with the steps of "manually programming said implanted device with … a plurality of interval rates over a specified period of time … [and then] said system determining a total dose over said specified period of time based on said basal rate and said interval rates."[2] The Specification describes the dose rate during any one time slot is the sum of a constant basal rate plus (or minus) a variable interval rate that captures any desired variance from the basal rate in that time slot. *See* Table II, paras. 36-38; *cf.* Table I (noting prior art schedule providing the same effective dosing as Table II, but expressed without basal/interval rate distinction).

[2] While the recitation of this step in claim 13 alludes to "said interval rate" in the singular, rather than the plural, this is ostensibly an inadvertent error, reading the claim in its entirety in light of the Specification, especially given the absence of any clear antecedent basis for "said interval rate" in the singular.

The Examiner rejected independent claims 1 and 13 as anticipated by Hartlaub or Fischell, and obvious in view of Boydman and Fischell. Appellants argue that Hartlaub, Fischell, and Boydman do not describe (or suggest) a step of "determining a total dose ... based on said basal rate and said interval rates" as recited in claims 1 and 13. Appeal Br. 14-15, 17, 18, 19, 20, 21, and 25.

Thus, the dispositive issue in this appeal is whether Hartlaub, Fischell, and/or Boydman describe a step of "determining a total dose ... based on said basal rate and said interval rates" as recited in claims 1 and 13.

OPINION

Claims 1 and 13 require "a basal rate" and "a plurality of interval rates over a specified period of time" to be "manually programm[ed]." The claims then require that the system "determin[e] a total dose over said specified period of time based on said basal rate and said interval rates." Of particular importance is that the total dose is determined *based on* the basal and interval rates. With this in mind, we determine, as discussed below, that none of the Examiner's rejections properly addresses the limitations of claims 1 and 13 requiring that the total dose is determined based on the basal and interval rates.

Rejection 1 - Hartlaub

In Hartlaub, a patient can self-administer additional bolus doses on demand to supplement a base drug flow rate. Para. 10. The frequency and amount of dosage can be limited through programmed limits. Para. 37. The actual total dosage delivered to the patient is tracked. Para. 40. If a patient nears the maximum daily dose, the program can deny or limit further bolus requests or prompt the patient to select a lower base rate. Para. 42. Thus,

the program in Hartlaub determines the total dose based on the actual dosage, not based on the base and bolus dosages. While the base and bolus dosage rates may affect the eventual, actual total dosage administered, the total dosage is not determined based on these rates. As such, we are persuaded that the Examiner erred in finding that Hartlaub describes a step of determining a total dose based on said basal rate and said interval rates as recited in claims 1 and 13. The Examiner's rejection of dependent claims 2-7 and 9-12 relies on the same erroneous finding. Consequently, we do not sustain the Examiner's rejection of claims 1-7 and 9-13 under § 102(e) as anticipated by Hartlaub.

Rejection II - Fischell

In Fischell, pre-programmed basal and supplemental dosage schedules are provided for a given period of time. Col. 6, ll. 57-60; fig. 21. At programmed times, the Fischell device administers a dose so long as neither a 3 hour nor a 24 hour limit is reached. Col. 30, ll. 34-43, col. 18, ll. 28-32. In order to determine if a limit is reached, the system counts the total dose over the specified periods of time based on the number of actual doses administered. Col. 18, ll. 10-13; col. 21, ll. 64-67 ("[t]he controller retrieves … pump actuation counts"). Consequently, Fischell's system determines the total dose based not on the basal and interval rates, but rather on the actual doses given by way of counted pump actuation counts. As such, we are persuaded that the Examiner erred in finding that Fischell describes a step of determining a total dose based on said basal rate and said interval rates as recited in claims 1 and 13. The Examiner's rejection of dependent claims 2-12 relies on the same erroneous finding. Consequently, we do not sustain the Examiner's rejection of claims 1-13 under § 102(b) as anticipated by Fischell.

Rejection III – Boydman and Fischell

In Boydman, a starting base infusion rate is programmed, as well as a supplemental interval dose amount and lockout interval. Col. 8, l. 50 to col. 9, l. 6. A patient can request an interval dose, subject to the lockout interval. Col. 5, ll. 14-26. A target number of requests per interval is programmed, and if the number of patient interval requests exceeds the target amount, the base rate is increased (vice versa if less), subject to certain total dose restrictions. Col. 5, ll. 30-44. While Boydman states that a preset dosage limit "will not be permitted to be exceeded" (col. 10, ll. 25-26), Boydman does not state the process by which the dosage limit is determined or avoided, nor is that process apparent from the disclosure. The Examiner does not make any additional findings or provide an analysis of the disclosures of Boydman or Fischell such as to make up this deficiency. Thus, we are persuaded that the Examiner erred in concluding that the teachings of Boydman and Fischell in combination render obvious a method as called for in claims 1 and 13, including the step of "determining a total dose … based on said basal rate and said interval rates." The Examiner relies on the same erroneous conclusion in rejecting dependent claims 2-10 and 12. Therefore, we do not sustain the Examiner's rejection of claims 1-10, 12, and 13 under § 103(a) as unpatentable in view of Boydman and Fischell.

DECISION

For the above reasons, we reverse Examiner's decision regarding rejections I, II, and III.

REVERSED

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